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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,953	09/10/2003	Alexander Karl Huwig	20959/2140 (P 63469)	3518

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

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09/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,953	<b>Applicant(s)</b> HUWIG ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,17-27,29 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) 5-10,13 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,11,12,14,15,17-20,27,29 and 33-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner acknowledges receipt of request for extension of time, request for examination under 37 CFR 1.114, declaration under 37 CFR 1.132, amendment and remarks filed 7/21/09. Claim 1 is amended. New claims 31 and 32 were added after final rejection on 5/20/09, which were not entered and new claims 33-43 are added. Claims 30-32 are canceled. Thus, claims 1, 2 and 4-15, 17-27, 29 and 33-43 are pending. Claims 5-10, 13 and 21-26 are withdrawn from consideration; claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27 and new claims 33-43 are under examination.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/09 has been entered.

2.

***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn in view of the amendment to claim 1.**

***Specification***

3. The disclosure is objected to because of the following informalities: 37 CFR 1.74 requires that where drawings/figures are filed, the specification disclosure should contain “Brief Description of Drawings” followed by brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals. This titled section is missing. However, if page 35, line 21 to page 36, line 2 is intended to be the description of the several views of the drawing and not just a discussion of Example 7, then the title “Brief Description of Drawings” is required between lines 19 and 21. However, “Brief Description Drawings” is requested to comply with the requirements of 37 CFR 1.174.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29 and 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540).

Hughes discloses liquid dentifrice and mouthwash compositions that comprise one or more of oral composition components that are selected from abrasives, binders such as xanthan gum and carboxymethylcellulose at 0.1-5%, humectants, surfactants, fluoride ion sources, anticalculus agents and sweeteners and additionally comprises dimethicone copolyol selected from alkyl- and alkoxy-dimethicone copolyols (abstract; column 5, lines 30-35, 52-65); may also include lipophilic flavorants and lipophilic antimicrobial compounds (column 4, lines 29-62). Silica gels or xerogels (column 6, line 10) or calcium carbonate (column 6, lines 22 and 23) are abrasive agents. The composition of Hughes may also contain surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55), anti-calculus agents, of which specific example is zinc compounds (column 6, line 59 to column 7 line 22), sweetening and flavoring agents at 0.005 to about 2% and humectants (column 7,

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lines 23-26, 43), bleaching agent (column 7, line 52 to column 8, line 45), optional agents such as dyes/colorant, pH adjusting agents, plant extracts and desensitizing agents such as potassium nitrate, and mixtures thereof (column 7, lines 27-41), and effervescent agents such as carbonate that are effective under acidic conditions and mixed with organic acids such as citric acid, malic acid, succinic acid and gluconic acid (column 8, lines 13-23). The composition may also contain polyethylene glycols (column 10, lines 60 and 61) and phosphonic acid chelating agents at 0.1-1% (column 12, line 16); and the composition contains from about 0-60% or 5-30% ethanol when it is a mouthwash (column 7, line 45) meeting claims 20 and 42. The xanthan gum and polyethylene glycol meet the limitation of polymer in claims 1, 12 and 36. The presence of phosphonic acid, citric acid meets the acid requirements of claims 1, 4, 11, 34 and 35. The fluoride ions meet the requirements of claims 14 and 37; potassium nitrate is a source of potassium ion meeting claims 15 and 38; carboxymethylcellulose meets the film-forming agent of claim 1; the sweetening agent at 0.005 to about 2% meets claims 19 and 41. Applying the composition containing desensitizing agent meets claim 27 and the composition of Hughes meets claims 18 and 40. The solubility of the acid recited in claims 2 and 33 is a property of the acid so that the acid of Hughes, which is the same phosphonic acid as in the claims, would have those properties and thus meet claims 2 and 33. Regarding claims 17 and 39, one film-forming agent may replace another without negatively affecting the composition. In this case, hydroxypropyl cellulose could be substituted for carboxymethyl cellulose with the expectation that the composition would be effective as a dentifrice.

Hughes discloses the claimed composition as described above. The difference between the Hughes composition and the claimed composition is that while Hughes teaches that the

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composition can be acidic, Hughes does not specifically teach a pH of from 1.5 to 3.5.

However, Asano describes dentifrice composition containing fluoride ion from potassium of sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). For claims 29 and 43, the artisan has the skills to adjust the pH of the composition to a value in which the fluoride ions are maintained in solution. Thus, when Hughes in view of Asano are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH of from 3.5 to 6 with the expectation of maintaining the fluoride and zinc ions in solution.

### ***Response to Arguments***

7. Applicant's arguments filed 7/21/09 have been fully considered but they are not persuasive.

8. Applicant argues that the claimed composition is a liquid while the composition of Hughes containing the acid is a solid because Hughes discloses the use of acid only in solid compositions because the acid and carbonate/bicarbonate react to generate carbon dioxide or oxygen.

9. The examiner disagrees with the applicant that the acid is present only in the solid composition in Hughes because Hughes specifically teaches that toothpastes, liquid dentifrices

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and denture cleansers in liquid or paste form generally contains abrasive polishing material (column 5, lines 52-56); that is denture cleansers or cleansing compositions are liquids or pastes. While tablet denture cleansing composition is preferred (column 8, lines 34-37), liquid denture cleansing compositions are also contemplated and the Hughes reference is not limited to the preferred embodiments. Also, the effervescence generators are effective under acid, neutral or alkaline conditions (column 8, lines 5-33) so that applicant's contention that acid must necessarily react with the effervescence generator is not supported by the disclosure of Hughes.

10. Applicant argues that Asano does not disclose or suggest compositions including non-polymeric acid and composition having a pH of 1.5 to 3.5 and that the composition of Asano has pH of 3.5-6.0 as disclosed in column 3, lines 17-19.

11. The examiner agrees with applicant that the Asano indicates that the pH of the composition should be maintained at 3.5 to 6.0. However, Asano is relied upon for teaching that pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). Asano's lower pH limit requirement meets the upper limit of the pH range required by the claims. Furthermore, the rejection is based on the combination of Asano and Hughes under 35 USC 103 and not anticipatory rejection under 35 USC 102.

12. Applicant argues that Asano does not provide reasons for lowering the pH within the claimed pH range and that the present claims restricting the pH to 2-3 is distinguished over Asano.

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13. The examiner disagrees with the applicant that the pH of the claimed composition is restricted to pH of 2-3 because claim 1 recites a pH range of from 1.5 to 3.5. Further Asano provides reasons for keeping the pH low because Asano teaches that the pH of the composition should be maintained low in order to prevent the fluoride from precipitating by specifically saying that the pH should be adjusted and the pH range taught in Asano indicates a variable pH adjustable to achieve desired composition for effective oral care. Secondly, a pH of 3.5 meets the upper pH limit of 3.5.

14. Applicant argues that the examiner used hind sight in combining Hughes with Asano because a skilled artisan would not have any incentive of combining the "components as defined in present claim 1," because applicant argues that even if combined as suggested, the proposed composition would be solid denture tablets or toothpastes since the examples in Hughes containing the acid are solids or toothpastes. Further, applicant argues that Examples VI to VII do not contain fluoride.

15. The examiner disagrees. The components of claim 1 were not combined to arrive at the claim 1. No hind sight reconstruction was made by the examiner because the skilled artisan would look to the suggestion of Asano to adjust pH of the composition of Hughes in order to maintain the fluoride ions in solution. Applicant says that Examples VI to VII do not contain fluoride ions and also that the denture compositions are solids in the Examples, but it is settled that a reference is not limited to its working examples, but must be evaluated for what it teaches (see *in re Boe*, 148 USPQ 507 (CCPA 1996) and *in re Chapman*, 148 USPQ 711 (CCPA 1966)). In the present case, Hughes contemplates compositions containing surfactants (column 6, lines

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34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55) and contemplates that the denture compositions can be liquid or solid.

16. Applicant argues that the desensitizers of the present invention differs from that of Hughes that is used daily, but daily use of desensitizer composition does not represent degrees of desensitization that may make the two compositions distinct. Since both the claimed and that disclosed by the prior art desensitize tooth, the two compositions are not distinct as desensitizers.

17. Applicant argues that Asano teaches away from the use of acid having protein and calcium precipitating properties because Asano prefers to use acids that do not cause precipitation and notes column 8, lines 21-26.

18. The examiner disagrees. Asano does not teach away using acids that would precipitate protein and calcium. As reproduced and referenced by applicant, Asano advocates that the pH of the composition should be such that the fluoride ions are kept in solution. Hughes teaches the acid of the claims and the property of the acid cannot be separated from the acid. Asano was not relied upon for using maleic acid.

19. Applicant's arguments are centered on the individual references and the main arguments have been failure of Asano to teach pH of 1.3 to 3.5 and the Hughes reference of teaching solid denture compositions. The examiner has addressed these arguments above. It is again noted that Asano is a secondary reference used to show that compositions containing fluoride ions are maintained at pH's in which the fluoride ions are in solution. Hughes, which is the primary reference, teaches compositions that contain phosphonic acid (column 12, line 16) and the phosphonic acid meets the limitation of the non-polymeric acid of claims 1, 4, 11, 18, 34, 35 and

40. And in response to applicant's arguments against the references individually, it is noted that

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one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

20. Declaration under 37 CFR 1.132 by Carlo Bolis:

21. Applicant argues on pages 10 and 11 of the remarks that the claimed composition is used to form massive plugs deep in the dentinal tubules to desensitize the tooth as demonstrated in applicant's specification at page 20, lines 1-8 and 17-23. But this demonstration on page 20, lines 1-8 and 17-23 has not compared the claimed composition with the composition of the prior art and the composition used in the plugging experiment is not claimed.

22. Applicant also refers to Example 5 and 8 having first component of phosphonic acid and a second component of polymer comprising polyacrylic acid and polyethylene glycol, hydroxypropyl cellulose and ethanol/water component. But while the composition of Example 5 is a specific composition that has not been claimed, applicant has not also compared the composition in Example 5 with the composition of the cited prior art. While Also, Example 8 studies the effect of desensitization of the specific composition of Example 5, the composition in the Example 5 is not the claimed composition and Example 8 does not compare the composition in Example 5 with the composition of the cited prior art.

23. Applicant refers to the declaration by Carlo Bolis as demonstrating that the pH of the composition of Example 8 prepared in accordance with the procedure of Example 5 has a pH of 2.7, which is within the claimed range of 1.5 to 3.5. But, a) a pH of 2.7 is but one point and representing the pH of one specific composition that is not the claimed composition (see claim

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1), b) the rejection was not that claim 1 cannot have a pH range of 1.5 to 3.5, c) applicant has not compared the composition having a pH of 2.7 with the composition of the cited prior art.

24. The declaration under 37 CFR 1.132 filed 7/21/09 is insufficient to overcome the rejection of claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29 and 33-43 based upon 35 USC 103 over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540) as set forth in the last Office action and reiterated herein and modified to address new claims 33-43 because: the composition used in the determination of the pH is not commensurate in scope with the claims and there is also no comparison with the composition of the prior art and the declaration is silent on the composition of the prior art.

25. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Blessing M. Fubara/  
Examiner, Art Unit 1618